

March 20, 1970

Dr. Myron Tribus
Assistant Secretary for Science and Technology
Department of Commerce
Washington, D. C. 20230

Dear Dr. Tribus:

Our discussion the other evening was a most rewarding experience, and I hope we have a chance for some encores.

I noticed in this morning's newspaper that the DOT is going to enforce the installation of air bags as a safety device in the very near future. It would be a wonderful thing if such a device could be made to work on a mass scale to meet the expectations of its proponents. I am, however, a little alarmed that such an innovation is going to be enforced very widely without, so far as I have been able to observe, any very extensive field trials. I wonder if you or your people have been given the opportunity to look at it as an arena for some of the approaches that we were discussing. Obviously there are many chances for mischief in a mass produced, mass installed system that will not be obviously apparent in experimental trials. For example, I wonder what a field day some mischievous vandals are going to have if they discover that they can trigger the device by tapping with a hammer. (Or is this going to be a way to insure that motorists really do lock up their cars!)

What perhaps concerns me the most is the level of reliability that is going to be demanded of the manufacturers. Unless there is some specific regulation on the point, it seems to me that the manufacturers are going to be stung for damages on any occasion that the air bag does not work, despite the fact that if ~~they have~~ been abused in many a way out of the manufacturer's control. I am not a stockholder in any automotive company, so my remarks are not based on an undue concern for their profits; I do want to be sure that demands are made on them that they are able to meet and can therefore have a productive outcome. Since I assume that ^{there} will be some definite relationship between reliability and price, there will be some nice problems in setting design standards. If this innovation turns out to be a fiasco on account of the way in which it is administered, it is going to give the whole field of safety technology a black eye, which ought to be avoided.

p177,164-6
198;A1104.

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May I also urge you to pay some attention to the definition of safety standards in connection with rather active proposals to revise the Delaney amendment.

Some material on these matters is enclosed.

Sincerely yours,

Joshua Lederberg
Professor of Genetics

* This supposition (i.e. if a hundred mice show no response we must be down to a no-effect level) contaminates what may seem to be a plausible critique. I would not object to extrapolation if the functional relationship of effect to dose were validly established at higher doses, and shown there to be non-linear. As you will well appreciate this is laden with statistical problems, and has almost never been properly done.

J. F.

Comments on the "Delaney Clause"
of the Food, Drug and Cosmetic Act
and on Senate Bill 3295, the proposed
"Food Additive Safety Act of 1970"
by
The Food Protection Committee of the
Food and Nutrition Board.
National Research Council.

February 25, 1970

* The scientific judgment of qualified experts, supported by information from animal tests concerning dietary levels of food chemicals known to produce no adverse effects, constitutes the basis for the evaluation of the safety of chemicals in food. Scientific judgment in evaluation of the safety of food and chemicals takes into consideration (a) dose-effect relationships, (b) the existence of no-adverse-effect levels, as demonstrated by animal tests, (c) knowledge of the metabolism, fate, and biochemical actions of the substances, (d) the application of adequate margins of safety, (e) where possible, practical experience with human exposure, and (f) an assessment of the risks and benefits involved.

→ I wish we had this too!

The "Delaney Clause" assumes that dose-response relationships and no-adverse-effect levels for carcinogenesis either do not exist or are without significance, and does not permit any latitude for scientific judgments of the safety of food chemicals with respect to carcinogenesis. Revision of that Clause to provide for exercise of sound, informed scientific judgment with respect to the possibility of carcinogenic risk to man seems to us a sounder and more practical approach to food safety than does the present rigid prohibition. For example, absolute prohibition of a substance "which is found to induce cancer in animals" mistakenly assumes that the carcinogenic property applies in all species at all dose levels and under all conditions of exposure. Rigid interpretation of the present Clause would indict many common and important foods that contain unavoidable traces of naturally occurring chemicals known to induce cancer in animals.